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OFFICE OF THE ATTORNEY GENERAL  
JUN 17 2002  
ATTORNEY DOCKET NO. 626-06-PA

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

George SACHS, et al.,

Serial No.: 10/080,113

Filed: February 21, 2002

For: COMPOSITIONS, TEST KITS  
AND METHODS FOR  
DETECTING HELICOBACTER  
PYLORI

Examiner: Unknown

Art Unit: 1645

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INFORMATION DISCLOSURE  
STATEMENT

Commissioner for Patents  
Washington D.C. 20231

Certificate of Mailing

I hereby certify that this correspondence is being deposited on June 13, 2002  
with the United States Postal Service as first class mail in an envelope  
addressed to Commissioner for Patents, Washington D.C. 20231.

*Maruzella Castro*  
Maruzella Castro  
June 13, 2002  
Date

Dear Sir:

Pursuant to 37 CFR Sections 1.97 and 1.98, and in fulfillment of the duty of candor set forth in 37 CFR Section 1.56, Applicant cites the following documents listed on Form 1449 which is submitted herewith. Copies of the references are enclosed.

- U.S. Patent No. 5,459,041 - Blaser, et al. - 10/17/95
- U.S. Patent No. 5,846,751 - Pronovost, et al., - 12/8/98
- U.S. Patent No. 5,859,219 - Cover, et al. - 1/12/99
- WO 96/26740 - Enteron Ltd. Partnership - 9/6/96
- WO 0056769 - Cambridge Life Sciences - 9/28/00

1. Aucher, et al., "Use of Immunoblot Assay To Define serum Antibody Patterns Associated with *Helicobacter pylori* Infection and with *H. pylori*-Related Ulcers", J. Clinical Microbiology (Apr. 1998) Vol. 36, No. 4: 931-936;

2. Andersen, et al., "Isolation and Preliminary Evaluation of a Low-Molecular-Mass

*Antigen Preparation for Improved Detection of Helicobacter pylori Immunoglobulin G Antibodies*", Clinical and Diagnostic Laboratory Immunology, (Mar. 1995) Vol. 2: 156-159;

3. Cullen, et al., "Serological Assessment of Helicobacter pylori Eradication", The Lancet (11/7/92); Vol. 340:1161-1162;
4. Hirschl, et al., "Kinetics of Specific IgG Antibodies for Monitoring The Effect Of Anti-Helicobacter pylori Chemotherapy", The Journal Of Infectious Diseases, (1993) Vol. 168: 763-6;
5. Kosunen, et al., "Diagnostic Value Of Decreasing IgG, IgA, and IgM Antibody Titres After Eradication Of Helicobacter pylori", The Lancet (4/11/92); Vol. 339:893-895;
6. Lerang, et al., "Accuracy of IgG Serology and Other Tests Confirming Helicobacter pylori Eradication", Scand J Gastroenterol 1998; 33: 710-715;
7. Lowry, et al., "Protein Measurement with the Folin Phenol Reagent", Dept of Pharmacology, Washington University, School of Medicine, St. Louis, MO (1951): 265-274;
8. Marshall, et al., "Unidentified Curved Bacilli In The Stomach Of Patients With Gastritis And Peptic Ulceration", The Lancet (6/16/84): 1311-1312;
9. Menegatti, et al., "Clinical Significance of Helicobacter pylori Seropositivity and Seronegativity in Asymptomatic Blood Donors", Digestive Diseases and Sciences, Vol. 43, No. 11 (Nov. 1998):2542-2548;
10. Menegatti, et al., "Helicobacter pylori In Patients With Gastric and Nongastric Cancer", The American Journal of Gastroenterology, Vol. 90, No. 8 (1995): 1278-1281;
11. Menegatti, et al., "Serological Response to Helicobacter pylori in Gastric and Non-Gastric Cancer", Clinical Science (1996) Vol. 91: 219-223;
12. Nishizono, et al., "Serological Assessment of the Early Response to Eradication Therapy Using an Immunodominant Outer Membrane Protein of Helicobacter pylori", Clinical and Diagnostic Laboratory Immunology, Vol. 5, No. 6 (Nov. 1998); 856-861;
13. Oderda, et al., "Eighteen Month Follow Up Of Helicobacter pylori Positive Children Treated With Amoxycillin And Tinidazole", Gut 1992; 33: 1328-1330;
14. Oderda, et al., "Serum Pepsinogen I and IgG Antibody to Campylobacter pylori In Non-Specific Abdominal Pain in Childhood", Gut 1989; 30:912-916;
15. Oderda, et al., "Helicobacter pylori in Children with Peptic Ulcer and Their

*Families*", Digestive Diseases and Sciences, Vol. 36, No.5 (May 1991):572-576;

16. Schagger, et al., "Tricine-Sodium Dodecyl Sulfate-Polyacrylamide Gel Electrophoresis for the Separation of Proteins in the Range from 1 to 100 kDa", Analytical Biochemistry, Vol. 166:368-379;

17. Tomb, et al., "The Complete Genome Sequence of the Gastric Pathogen *Helicobacter pylori*", Nature, Aug. 1997; Vol. 388:539-547;

18. Vaira, et al., "Antibody Titres to *Campylobacter pylori* After Treatment for Gastritis", BMJ; Aug. 1988; Vol. 297:397;

19. Vaira, et al., "*Helicobacter pylori* Status, Endoscopic Findings, and Serology in HIV-1-Positive Patients", Digestive Diseases and Sciences; Vol. 40, No.8: 1622-1626;

20. Vaira, et al., "Serum Immunoglobulin G Antibody Levels for *Campylobacter pylori* Diagnosis", Gastroenterology; Vol. 97, No.4: 1069-1070;

21. Vaira, et al., "Screening for *Helicobacter pylori*", The Lancet, Vol. 338; Nov. 1991:1149;

22. Vaira, et al., "Prevalence of Peptic Ulcer in *Helicobacter pylori* Positive Blood Donors", Gut, 1994; 35:309-312;

23. Vaira, et al., "*Campylobacter pylori* in Abattoir Workers: Is It A Zoonosis?", The Lancet, Sept. 1988:725-726;

24. Volland, et al., "Identification of Antigens of *Helicobacter pylori* That can Be Used As Markers For Diagnosis And Monitoring Eradication In Patients Based On A Serological Method", XP-002145286.

REMARKS

Submission of the foregoing documents is no representation that a search was made, or if made, that it was comprehensive, or that no other documents exist which may be material to the above-identified application. Moreover, the Applicant does not concede that the foregoing documents are necessarily prior art to the invention.

Date: June 13, 2002

By: Gabor L. Szekeres  
Gabor L. Szekeres  
Registration No. 28,675

LAW OFFICES OF GABOR L. SZEKERES  
8144 E. Kaiser Boulevard, Suite 112  
Anaheim, CA 92808  
Telephone: (714) 998-3295

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**1645**

## U.S. PATENT DOCUMENTS

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**FOREIGN PATENT DOCUMENTS**

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**OTHER DOCUMENTS (Including author, Title, Date, Pertinent Pages, Etc.)**

	Aucher, et al., "Use of Immunoblot Assays To Define serum Antibody Patterns Associated with <i>Helicobacter pylori</i> Infection and with <i>H. pylori</i> -Related Ucers", J. Clinical Microbiology (Apr. 1998) Vol. 36, No. 4: 931-936;
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